UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CITY OF LIVONIA EMPLOYEES' RETIREMENT SYSTEM, on behalf of itself an all others similarly situated,

Plaintiffs,

-v-

WYETH ESSNER, *et al.*,

Defendants.

No. 07 Civ. 10329 (RJS)
ORDER

RICHARD J. SULLIVAN, District Judge:

Before the Court is a motion by Lead Plaintiff Pipefitters Union Local 537 Pension Fund and Plaintiff City of Livonia Employees' Retirement System (collectively, "Plaintiffs") to strike: (1) four exhibits submitted by Defendants in connection with their motion to dismiss the Consolidated Complaint, and (2) certain arguments raised by Defendants in their reply submission. Specifically, Plaintiffs move to strike exhibits 1, 2, 3, and 5 of the August 25, 2008 Declaration of Michael J. Chepiga, Esq., which was filed with Defendants' reply submission in support of their motion to dismiss (the "Chepiga Decl." (Doc. No. 32)), as well as Defendants' arguments regarding exhibit 4 of the Chepiga Declaration. For the reasons set forth below, Plaintiffs' motion is granted in part and denied in part.

I. Background

Below the Court recites only those facts that are relevant to the parties' arguments regarding the instant motion. Nothing in this Order constitutes a finding of fact or a conclusion on the merits with respect to Defendants' pending motion to dismiss.

A. Facts

In this putative class action, Plaintiffs claim that, between June 26, 2006 and July 24, 2007 (the "Class Period"), Defendants made fraudulent misrepresentations and omissions regarding a pharmaceutical product known as Pristiq, for which Defendant Wyeth Essner ("Wyeth") sought regulatory approval from the Food and Drug Administration (the "FDA"). (*See* Consolidated Compl. ("Compl.") ¶¶ 2, 3.) Based on these allegations, Plaintiffs bring two causes of action pursuant to the Securities Exchange Act of 1934, 15 U.S.C. § 78 *et seq.* (the "Exchange Act").

Wyeth developed Pristiq as a treatment for, among other things, post-menopausal vasomotor symptoms ("VMS"). (Compl. ¶¶ 16, 25.) Prior to the Class Period, Wyeth initiated Phase 3 clinical trials of Pristiq's safety and efficacy as a treatment for VMS. (*Id.* ¶ 6.) In December 2003, Wyeth began "Study 315," a randomized study of Pristiq that was conducted on women between the ages of thirty-seven and seventy-eight in thirty-seven locations throughout the country. (*Id.* ¶ 23.) According to Plaintiffs, there were twenty-seven instances of "serious adverse events" ("SAEs") reported by test subjects during Study 315. (*Id.* ¶ 25.) The reported SAEs allegedly included liver damage, hypertension, heart attacks, and arterial obstruction. (*Id.*; *see also id.* ¶ 78.)

Plaintiffs allege that Wyeth completed its review and analysis of the Study 315 data in May 2005. (*Id.* ¶ 23.) In June 2006, Wyeth submitted a new drug application ("NDA") to the FDA seeking approval for the use of Pristiq as a treatment for VMS (the "VMS NDA"). (*Id.* ¶ 25.) Plaintiffs allege that "[t]he safety data associated with Study 315 [was] submitted to the FDA" as part of the VMS NDA. (*Id.*) However, Plaintiffs argue that Defendants concealed from the public the SAEs that occurred during Study 315, and made false and misleading

statements about the likelihood that the Pristiq VMS NDA would be approved. In support of these allegations, Plaintiffs point to a slide presentation given by Wyeth on October 5, 2006 at its annual conference for analysts and investors. (*Id.* ¶ 69.) Plaintiffs argue that the use of slides praising Pristiq as a safe and effective treatment for VMS, without disclosing the SAEs, constituted a material omission in violation of the Exchange Act. (*Id.* ¶ 78.)

Plaintiffs assert that Defendants undertook this fraudulent scheme in an attempt to overcome financial problems arising out of Wyeth's difficulty in developing new products and the imminent expiration of the patents on Wyeth's older drugs. Plaintiffs argue that one source of the economic difficulty faced by Wyeth, and other pharmaceutical manufacturers, was that the FDA was increasingly rejecting NDAs for drugs that were in the later stages of development. (*Id.* ¶ 10.) Plaintiffs refer to this phenomenon as the "pipeline problem," and they allege that it is "well known, has been widely discussed in the media and has been a major issue for all pharmaceutical companies . . . ." (*Id.*)

II. Legal Standard

When resolving a motion to dismiss pursuant to Rule 12(b)(6), courts are permitted to consider documents that are attached to the complaint, materials that are incorporated into the pleading by reference, and matters of which judicial notice may be taken. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007); *Rothman v. Gregor*, 220 F.3d 81, 88 (2d Cir. 2000). A document may be deemed to be incorporated into a complaint by reference when the pleading contains extensive quotes from the document. *See, e.g.*, *Mangiafico v. Blumenthal*, 471 F.3d 391, 398 (2d Cir. 2006). Courts may also consider documents the "terms and effect" of which plaintiffs strongly rely upon in making their allegations. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002). Indeed, even if the plaintiffs only

reference selected portions of a document, courts are permitted to consider the text in full if it may properly be deemed integral to the pleading. *San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 808-09 (2d Cir. 1996). However, "[l]imited quotation does not constitute incorporation by reference." *Goldman v. Belden*, 754 F.2d 1059, 1066 (2d Cir. 1985); *see also Sira v. Morton*, 380 F.3d 57, 67 (2d Cir. 2004).

III. Discussion

Plaintiffs move to strike the media articles submitted by Defendants as exhibits 1, 2, and 3 of the Chepiga Declaration, as well as exhibit 5, which is the Clinical Study Report regarding Study 315. Additionally, although Plaintiffs do not challenge the document itself, they move to strike Defendants' arguments based on exhibit 4 of the Chepiga Declaration, which contains excerpts from Wyeth's October 5, 2006 slide presentation to analysts and investors. For the reasons set forth below, Plaintiffs' motion to strike exhibits 1, 2, and 3 is granted, and the motion is denied as to exhibit 5 and Defendants' arguments regarding exhibit 4.

A. Exhibits 1, 2, and 3

Exhibits 1, 2, and 3 to the Chepiga Declaration are news articles from *Pharmaceutical Executive*, *Fortune*, and *The Wall Street Journal*. Defendants submitted the articles in support of their contention that "Wyeth was subject to a tighter [FDA] approval process than could have been historically anticipated." (Defs.' Mem. at 8 (internal quotation omitted).) In opposition to Plaintiffs' instant motion, Defendants present two arguments in support of their position that these articles are properly before the Court. First, Defendants assert that the articles support "the exact same proposition" that Plaintiffs have alleged in paragraph 10 of the Consolidated Complaint. (*Id.*) Second, they contend that Plaintiffs' "express reference to 'media' reports

brings the news articles directly within the scope of Plaintiffs' allegations." (*Id.*) Neither of these arguments is persuasive.

To the extent that Defendants merely seek to rely on "the exact same proposition" alleged by Plaintiffs in paragraph 10 of the Consolidated Complaint, they need not provide extraneous support for it. The Court will assume, as it must, the truth of Plaintiffs' allegations when resolving Defendants' motion to dismiss. *See, e.g.*, *Deniran v. Mattingly*, No. 07 Civ. 6159 (RJS), 2009 WL 857621, at *1 (S.D.N.Y. Mar. 31, 2009). Moreover, the mere mention of the word "media" is insufficient to deem articles of Defendants' choosing to be incorporated by reference into the Consolidated Complaint. *See B.V. Optische Industrie De Oude Delft v. Hologic, Inc.*, 909 F. Supp. 162, 167 (S.D.N.Y. 1995) (concluding that a "clear and definite reference to extraneous submissions" is required for the court to consider them when ruling on a motion to dismiss). Defendants have not argued that the Court could properly take judicial notice of the articles, and Plaintiffs' reference to "media" constitutes nothing more than an indefinite allegation regarding news coverage of the "pipeline phenomenon." The allegation is not the type of "clear and definite" reference that would allow the Court to consider the articles submitted by Defendants. *See Chambers*, 282 F.3d at 153. Accordingly, Plaintiffs' motion to strike exhibits 1, 2, and 3 of the Chepiga Declaration is granted.

B. Exhibit 5

Exhibit 5 to the Chepiga Declaration is Wyeth's January 18, 2006 Clinical Study Report relating to Study 315 (the "Report"), which is titled "Final Report: A Double-Blind, Randomized, Placebo Controlled Efficacy and Safety Study of DVS SR for the Relief of Vasomotor Symptoms Associated with Menopause." Defendants submitted the Report in

support of their argument that they had no duty to disclose the results of Study 315 because, "[a]s a factual matter, the cardiac, hepatic and hypertension outcomes that Plaintiffs cite are not statistically significant." (Doc. No. 31 at 7.)

In their motion to strike, Plaintiffs argue that they did not previously have access to the Report, and that Defendants seek to "improperly use the document to challenge the Complaint's falsity allegations." (Pls.' Mem. at 6.)[1] However, "[e]ven where a document is not [expressly] incorporated by reference, the court may nevertheless consider it where the complaint 'relies heavily upon its terms and effect' . . . ." *Chambers*, 282 F.3d at 153 (quoting *Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995)). There can be no question that the VMS NDA is central to this action (*see, e.g.*, Compl. ¶ 3), and Plaintiffs do not dispute that the Report was part of Wyeth's VMS NDA. Indeed, they acknowledge that "the safety data associated with Study 315 [was] submitted to the FDA in June 2006 along with the Pristiq NDA for the VMS indication . . . ." (*Id.* ¶ 24.)

Moreover, when making their allegations, Plaintiffs rely on the existence of Wyeth's analysis of the results of Study 315. Specifically, Plaintiffs allege that "Wyeth's biostatistics group carried out the statistical analysis of Pristiq's efficacy, safety, and tolerability data gathered during both the therapy and post-therapy periods," and that this analysis was submitted to the FDA. (*Id.*) Plaintiffs then make numerous allegations regarding the "results of Study

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[1] In their reply submission, Plaintiffs also challenge, for the first time, the authenticity of the Report. (Pls.' Reply Mem. at 2-3.) However, a movant may not raise new arguments in a reply submission. *See, e.g.*, *In re South African Apartheid Litig.*, No. 02 Civ. 4712 (SAS), 2009 WL 1579093, at *3 n.29 (S.D.N.Y. May 27, 2009). Plaintiffs are aware of this legal proposition, as they invoke it themselves in challenging Defendants' reply submission in support of the motion to dismiss. (Pls.' Mem. at 7.) In any event, the Chepiga Declaration states that exhibit 5 is "a true and correct copy" of the Report. (Chepiga Decl. ¶ 6.) Plaintiffs articulate no specific basis for questioning either that representation or the actual authenticity of the Report. Therefore, even if this argument were properly before the Court, it would be rejected.

315." For example, Plaintiffs allege that "[d]espite submitting the Study 315 data to the FDA, defendants failed to disclose publicly the negative safety results of the study or reveal the existence or nature of the SAEs . . . ." (*Id.* ¶ 31; *see also id.* ¶ 67 (making allegations regarding the "results of Study 315"); *accord id.* ¶¶ 78, 84, 90, 95, 105.) Thus, although Plaintiffs do not refer to the Report by name in the Consolidated Complaint, they rely on Wyeth's conclusions regarding the results of Study 315 as one of the bases for their claims. Therefore, the VMS NDA — in its entirety, and including the Report — is hereby deemed to be incorporated into the Consolidated Complaint by reference. Accordingly, Plaintiffs' motion to strike Exhibit 5 of the Chepiga Declaration is denied.

C. Defendants' Arguments Based on Exhibit 4

Exhibit 4 of the Chepiga Declaration consists of excerpts from a slide presentation given at Wyeth's October 5, 2006 annual conference for analysts and investors. Defendants rely on the document for their argument that "the contents of the slides . . . flatly contradict" some of Plaintiffs' allegations. (Defs.' Mem. at 6.) Plaintiffs do not move to strike Exhibit 4 itself. Rather, they seek to have Defendants' *arguments* regarding the exhibit stricken because they were improperly presented for the first time in their reply submission, and, in Plaintiffs' view, Defendants have mischaracterized the slides. (Pls.' Mem. at 7.) Simply put, these arguments are unavailing.

Defendants' arguments based on exhibit 4 were not raised for the first time in their reply. In the opening brief in support of their motion to dismiss, Defendants argued that Wyeth had "disclosed to the market" all of the facts that Plaintiffs allege were omitted, including "the incidence of hypertension in the treatment group of Study 315 . . . ." (Doc. No. 24 at 18-19.) In

their reply submission, Defendants asserted that "[w]ith respect to hypertension, Wyeth disclosed that outcome in the October 2006 analysts presentation . . . ." (Doc. No. 31 at 11 (citing Chepiga Decl. Ex. 4).) Therefore, in their reply, Defendants merely sought to bolster their initial argument by citing to exhibit 4. *See In re World Trade Center Disaster Site Litig.*, No. 21 MC 100 (AKH), 2008 WL 2704317, at *1 (S.D.N.Y. July 10, 2008) (finding that arguments in movant's reply merely "reinforced their original arguments"). Therefore, Plaintiffs' first argument is factually incorrect.

Plaintiffs' second contention — that Defendants have mischaracterized the contents of exhibit 4 — is simply a challenge to the merits of Defendants' argument that is, in essence, an unauthorized sur-reply. This is not an appropriate basis for striking a portion of Defendants' reply, and the Court will address the merits of Defendants' argument in connection with the resolution of their motion to dismiss. Accordingly, Plaintiffs' motion to strike Defendants' arguments based on exhibit 4 is denied.

IV. Conclusion

For the foregoing reasons, Plaintiffs' motion to strike is granted in part and denied in part. The Clerk of the Court is respectfully directed to terminate the motion docketed as document number 33.

SO ORDERED.

Dated: June 25, 2009
New York, New York

RICHARD J. SULLIVAN
UNITED STATES DISTRICT JUDGE